

U.S.S.N. 10/082,954

Filed: February 26, 2002

## AMENDMENT AND RESPONSE TO OFFICE ACTION

## In the Claims

1. (canceled)
2. (currently amended) The device of claim + 30 wherein the chemical composition of the polyhydroxyalkanoate is altered through selection of monomers which are incorporated into the polymer, by alteration of the linkages, chemical backbone or pendant groups, ~~or by manipulation of the molecular weight.~~
3. (currently amended) The device of claim + 30 wherein the polyhydroxyalkanoate composition comprises ~~additive~~ additives altering the degradation rate of the composition, wherein the additives are selected from the group consisting of hydrophilic substances, hydrophobic substances, and coating which alter water uptake by the composition.
4. (currently amended) The device of claim + 30 wherein the polyhydroxyalkanoate comprises a polymer selected from the group of consisting of poly-4-hydroxybutyrate, poly-4-hydroxybutyrate-co-3-hydroxybutyrate, poly-4-hydroxybutyrate-co-2-hydroxybutyrate, and copolymers and blends thereof.
5. (currently amended) The device of claim + 30 wherein the polyhydroxyalkanoate comprises a polymer selected from the group consisting of poly-3-hydroxybutyrate-co-3-hydroxyhexanoate, poly-3-hydroxybutyrate-co-3-hydroxyoctanoate, poly-3-hydroxybutyrate-co-3-hydroxydecanoate, and copolymers and blends thereof.
6. (currently amended) The device of claim + 30 wherein the polyhydroxyalkanoate comprises one or more units which alter the chemical stability of the polymer backbone.

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7. (currently amended) The device of claim 1 30 comprising unit(s) promoting chain scission.
8. (original) The device of claim 7 wherein the units contain more than two functional groups.
9. (currently amended) The device of claim 1 30 wherein a heteroatom is incorporated into the polymer backbone chain.
10. (original) The device of claim 9 wherein the heteroatom is selected from the group consisting of oxygen, sulfur or nitrogen.
11. (original) The device of claim 7 wherein the units are incorporated into the polymer backbone with chemical linkages selected from the group consisting of ester, amide, ether, carbamate, anhydride, and carbonate.
12. (currently amended) The device of claim 11 wherein the units are selected from the group consisting of 2-hydroxyacids, 2-hydroxyalkoxyacetic acids, amino acids, amino alcohols, diacids, triols, and tetraols.
13. (currently amended) The device of claim 12 wherein the 2-hydroxyacids are 2-hydroxalkanoic acids.
14. (original) The device of claim 13 wherein the 2-hydroxyalkanoic acid is lactic acid or glycolic acid.
15. (canceled)

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16. (original) The device of claim 12 wherein the 2-hydroxyalkoxyacetic acids are selected from the group consisting of 2-hydroxyethoxy acetic acid and 3-hydroxypropoxy acetic acid.
17. (currently amended) The device of claim + 30 wherein the polymer comprises pendant groups that catalyze the degradation of the polymer backbone.
18. (original) The device of claim 17 wherein the pendant groups are selected from acidic and basic groups.
19. (original) The device of claim 17 comprising reactant pendant groups that cause polymer chain scission.
20. (original) The device of claim 19 wherein the reactant pendant groups are selected from nucleophiles and electrophiles.
21. (original) The device of claim 17 wherein the pendant groups are selected from the group consisting of alcohols, acids, and amine groups.
22. (currently amended) The device of claim + 30 comprising additives altering the chemical stability of the polyhydroxyalkanoate.
23. (original) The device of claim 22 wherein the additives promote chain scission.
24. (original) The device of claim 22 wherein the additives are selected from the group consisting of acids, bases, electrophiles, nucleophiles, plasticizers, polymers, pore forming agents, and agents designed to reduce the polymer crystallinity.
25. (currently amended) The device of claim + 30 comprising pore forming agents.

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26. (original) The device of claim 25 wherein the pore forming agents are lyophilizable particles.
27. (original) The device of claim 25 wherein the pore forming agents absorb water.
28. (currently amended) The device of claim ~~1~~ 30 further comprising one or more active agents.
29. (original) The device of claim 28 wherein the active agent is selected from the group consisting of growth factors, alginates, silver salts, antiseptics, analgesics, and preservatives.
30. (currently amended) A device comprising a biodegradable polyhydroxyalkanoate polymer composition that has a controlled degradation rate of ~~less than two years, preferably less than one year, under physiological conditions,~~  
wherein the degradation ~~rates~~ rate of the ~~polyhydroxyalkanoates~~ polyhydroxyalkanoate ~~polymer are~~ is manipulated through addition of components to the polymeric composition, selection of the chemical composition, molecular weight, processing conditions, or form of the composition, ~~as defined by any of claims 1-29,~~  
wherein the polyhydroxyalkanoate polymer has a molecular weight of between 10,000 and 10,000,000 Daltons,  
wherein the average molecular mass loss of the polymer decreases 20% to 50% over a ten week time period *in vivo*, and

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wherein the device is selected from the group consisting of sutures, suture fasteners, meniscus repair devices, rivets, tacks, staples, screws, bone plates and bone plating systems, surgical mesh, repair patches, slings, cardiovascular patches, orthopedic pins, adhesion barriers, stents, guided tissue repair/regeneration devices, articular cartilage repair devices, nerve guides, tendon repair devices, atrial septal defect repair devices, pericardial patches, bulking and filling agents, vein valves, bone marrow scaffolds, meniscus regeneration devices, ligament and tendon grafts, ocular cell implants, spinal fusion cages, skin substitutes, dural substitutes, bone graft substitutes, bone dowels, wound dressings, and hemostats.

31. (currently amended) A method for making a device that has a controlled degradation rate of less than two years, more preferably less than one year under physiological conditions, comprising providing ~~comprising~~ a biocompatible polyhydroxyalkanoate composition, as defined by claim ~~4~~, 30 and

forming or incorporating the polyhydroxyalkanoate composition into a device selected from the group consisting of sutures, suture fasteners, meniscus repair devices, rivets, tacks, staples, screws, bone plates and bone plating systems, surgical mesh, repair patches, slings, cardiovascular patches, orthopedic pins, adhesion barriers, stents, guided tissue repair/regeneration devices, articular cartilage repair devices, nerve guides, tendon repair devices, atrial septal defect repair devices, pericardial patches, bulking and filling agents, ligament and tendon grafts, ocular cell implants, spinal fusion cages, skin substitutes, dural

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substitutes, bone graft substitutes, bone dowels, heart valves and vascular grafts, wound dressings, and hemostats.

32. (original) The method of claim 31 wherein the processing forming or incorporating process is selected from the group consisting of solvent casting, melt processing, fiber processing, fiber spinning, fiber weaving, extrusion, injection molding, compression molding, lamination, and microparticle formation.

33. (original) The method of claim 31 further comprising incorporating an active agent into the polyhydroxyalkanoate.